UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
CHEMICAL SAFETY AND
POLLUTION PREVENTION

MEMORANDUM:

To: Kable Bo Davis, PM03

From: Matthew Aubuchon, Ph.D., Entomologist

Secondary Review: Jennifer Saunders, Ph.D., Acting Senior Entomologist

Date: 11/9/16

Subject: PRODUCT PERFORMANCE DATA EVALUATION RECORD (DER)

THIS DER DOES NOT CONTAIN CONFIDENTIAL BUSINESS INFORMATION

Note: MRIDs found to be **unacceptable** to support label claims should be removed from the data matrix.

DP barcode: 387393
Decision no.: Rereg
Submission no: Rereg
Action code: Rereg
Product Name: Bengal Product 2007A
EPA Reg. No or File Symbol: 68543-35
Formulation Type: Aerosol Fogger
Ingredients statement from the label with PC codes included:
Phenothrin 2.00% PC: 069005

Application rate(s) of product and each active ingredient (lbs. or gallons/1000 square feet or per acre as appropriate; and g/m$_2$ or mg/cm$_2$ or mg/kg body weight as appropriate): Cans contain 8.1 oz (2296 g) of product which is dispersed into a maximum volume of space measuring 6000 ft^3. Label recommends area be unobstructed. A sample room measuring 24'length x 25'width by x 10' high would achieve proper volume. For flea control, one canister should be deployed into unobstructed area measuring 3000 ft3, with sample room dimensions provided at 20' long x 15'wide x 10'high. Applications may not be dispersed in areas less than 5'x 5'.

Use Patterns: Indoor applications for residential sites and/or homes such as apartments, condominiums, attics, closed porches, cabins, garages, kitchens, pet sleeping areas, and rooms.

Label mentions boats but does not specify if the boats are to be enclosed within a structure or if applications may be dispersed within the living space of larger boats (yachts, house boats, etc.).

It is important to remove pets and people from the treatment area for at least two hours, turn off pilot lights, and unplug appliances from electrical outlets prior to application. Not for use in commercial or industrial buildings.

I. Action Requested: Reregistration efficacy review requested. MRIDs 45590804, 47697301, 47385001, 44145101, and 45407804 are listed on the data matrix for this product and are reviewed here to determine if efficacy claims against fleas, ticks, ants, lice, mosquitoes, flies, gnats, wasps, hornets, bees, and yellow jackets are supported.

II. Background: Product specific data were called in for phenothrin to support the reregistration of this product.

III. MRID SUMMARY

MRID 45590804 contains 8 studies investigating efficacy against black widow spiders, brown dog ticks, cat fleas, centipedes, fire ants, mosquitoes (*Aedes aegypti* only), scorpions, and yellow jackets. Because the flea, tick, fire ants, mosquitoes, and yellow jacket studies pertain to the subject product, data for black widow spiders, centipedes, and scorpions are not reviewed here.

MRID 47697301 investigated the knockdown efficacy of a fogger against cat fleas *Ctenocephalides felis.* Test product for MRID was Bengal Product 2007A (EPA Reg. No. 68543-35).

MRID 47385001 investigated the knockdown efficacy of a fogger against American cockroaches (*Periplaneta americana*), body lice (*Pediculus humanus humanus*), bedbugs (*Cimex lectularius*), cat fleas (*Ctenocepahlides felis*), and yellow jackets (*Vespula maculifrons*). Test product for MRID was Bengal Product 2007A (EPA Reg. No. 68543-35).

MRID 44145101 investigated the efficacy of formulations F-2471 (2% phenothrin) and TOAPS (0.2% phenothrin; 1.6% piperonyl butoxide) against German cockroaches *Blatella germanica*, and harvester ants (no species specified). In separate tests, formulations F-2471 and OAT-II were tested against cat fleas *Ctenocephalides felis* and brown dog ticks *Rhipicephalus sanguineus*. Contents of the formulation OAT-II were not disclosed. Experimental design for all tests evaluated efficacy when used as direct-spray applications.

MRID 5407804 investigated direct spray applications of formulations F-21281 (0.4% phenothrin) and X-54241 (0.4% phenothrin; 1.6% MGK 264) against the human body louse *Pediculus humanus humanus.* Fabric surfaces were directly sprayed with test formulations, then mortality was recorded over a period of 24 hours.

45590804. Product Performance/Efficacy Testing in Support of Multicide Wasp & Hornet Killer 20861 EPA Reg. No. 1021-.

A. Pressurized Spray Efficacy – Brown Dog Ticks

(1) non-GLP

(2) **Methods:** None of the three test substances contained the same active ingredients as the subject product (2.0% phenothrin), therefore no review was conducted for brown dog tick data (*Rhipicephalus sanguineus*). Test formulations consisted of the following: TL-4485 (0.1% phenothrin; 0.075% ETOC; 0.5% piperonyl butoxide); TOAPS (0.2% pyrethrin; 1.6% piperonyl butoxide); F-2086 (0.2% phenothrin; 0.2% tetramethrin). The experimental methods consisted of direct substrate spraying whereas 68543-35 is a spatial fogger.

(3) **Results:** No review was conducted on these data.

(4) **Conclusion:** This study does not support that the subject product 68543-35 kills brown dog ticks because use patterns and active ingredients of the test formulations did not match the subject product.

B. Pressurized Spray Efficacy – Cat Fleas

(1) non-GLP

(2) **Methods:** None of the three test substances contained the same active ingredients as the subject product (2.0% phenothrin), therefore no review was conducted for cat flea data (*Ctenocephalides felis*). Test formulations consisted of the following: TL-4485 (0.1% phenothrin; 0.075% ETOC; 0.5% piperonyl butoxide); TOAPS (0.2% pyrethrin; 1.6% piperonyl butoxide); F-2086 (0.2% phenothrin; 0.2% tetramethrin). The experimental methods consisted of direct substrate spraying whereas 68543-35 is a spatial fogger.

(3) **Results:** No review was conducted on these data.

(4) **Conclusion:** This study does not support that the subject product 68543-35 kills cat fleas because use patterns and active ingredients of the test formulations did not match the subject product.

C. Fire Ant Spray Evaluation

(1) non-GLP

(2) Methods: None of the four test substances contained the same active ingredients as the subject product (2.0% phenothrin), therefore no review was conducted for fire ant data (*Solenopsis invicta*). Test formulations consisted of the following: F-2577 (0.2% tetramethrin; 0.3% esfenvalerate); F-2695 (0.2% tetramethrin; 0.125% phenothrin); F-2611 (0.05% pyrethrins; 0.1% piperonyl butoxide; 0.167% MGK®264; 0.1% esfenvalerate); F-27301 (0.1% ETOC; 0.5% MGK®264). The experimental methods consisted of direct substrate spraying whereas 68543-35 is a spatial fogger.

(3) Results: No review was conducted on these data.

(4) **Conclusion:** This study does not support that the subject product 68543-35 kills fire ants because use patterns and active ingredients of the test formulations did not match the subject.

D. Pressurized Spray Efficacy – Mosquitoes

(1) non-GLP

(2) **Methods:** None of the three test substances contained the same active ingredients as the subject product (2.0% phenothrin), therefore no review was conducted for mosquito data (*Aedes aegypti*). Test formulations consisted of the following: TL-4485 (0.1% phenothrin; 0.075% ETOC; 0.5% piperonyl butoxide); TOAPS (0.2% pyrethrin; 1.6% piperonyl butoxide); F-2086 (0.2% phenothrin; 0.2% tetramethrin). The experimental methods consisted of direct substrate spraying whereas 68543-35 is a spatial fogger.

(3) **Results:** No review was conducted on these data.

(4) **Conclusion:** This study does not support that the subject product 68543-35 kills mosquitoes because use patterns and active ingredients of the test formulations did not match the subject.

E. Evaluation of Three Formulations for Jet Stream Knockdown and Kill of Wild Stinging Hymenopterans ("Yellow Jackets").

(1) non-GLP

(2) **Methods:** None of the three test substances contained the same active ingredients as the subject product (2.0% phenothrin), therefore no review was conducted for yellow-jacket data (*Vespula germanica*). Formulations of test substances consisted of the following: S10181 (0.20% phenothrin; 0.2% tetramethrin); S10183 (0.10% phenothrin; 0.10% tetramethrin); Real Kill Wasp & Hornet Killer (EPA Reg No. 9688-117-478) (undisclosed active ingredient). The experimental methods consisted of direct substrate spraying whereas 68543-35 is a spatial fogger.

(3) **Results:** A review of the yellow-jacket data was not conducted.

(4) **Conclusion:** This study does not support that the subject product 68543-35 kills yellow jackets because use patterns and active ingredients of the test formulations did not match the subject.

MRID 45590804: This study is **unacceptable** and should be removed from the data matrix for 68543-35. Test formulations contained different active ingredients, multiple active ingredients, and/or synergists. Therefore efficacy data could not be bridged to support claims on subject product 68543-35. Use patterns of test formulations were designed for direct-spray applications. In contrast, the use pattern of 68345-35 is a spatial fogger. This

inconsistency further prohibits the bridging of data from MRID 45590804 to support the subject product 68543-35.

47697301. An Evaluation of the Efficacy of a Total Release Aerosol (Fogger) against Cat Fleas

(1) non-GLP

(2) **Methods:** Ten adult cat fleas (*Ctenocephalides felis*) were placed in a plastic five-gallon arena. Four (4) replicate arenas were designated for fogger tests; four (4) arenas were designated as untreated controls for each treatment. Arenas consisted of 18-gal tubs (19.25"L x 16.25"W x 16"H) lined with carpeting. All arenas were placed symmetrically around a partitioned test chamber measuring 8' x 15' (6000 ft^3). Total volume of treated space was 3000 ft^3 within partition. Three separate treatments were conducted. Test arenas were removed from the treatment chambers after 4 hours. Insects remained within test arenas for duration of data collection. Product was discharged at a height of 30" above the floor for an average of 1 minute, 20 seconds and dispensed an average of 76.46 grams of material. Insects were left in treatment chamber for a period of four hours, then transported to a separate untreated laboratory. All insects remained in their original containers throughout the study. Percent (%) mortality was calculated after 4, 24, and 48 hrs post treatment.

(3) **Results:** Flea mortality was 0% after four hours, then <1% after 24 hrs post treatment. The 48-hr count however resulted in an average of 93.7% flea mortality. No control mortality was observed.

(4) **Conclusion:** This study supports claims against fleas.

MRID 47697301: This study is **acceptable** and should remain on the data matrix for product 68543-35. Claims must not exceed a volume of 3000 ft^3 which corresponds to the space in which treatments were conducted. Reviewer notes that in previous studies, failure to remove insects from the treatment arena would invalidate the study because continued exposure would not represent a realistic scenario. However, in this case, retaining fleas inside carpeted areas represents a real-world scenario for residential dispersal of a fogger.

47385001. An Evaluation of the Efficacy of a Total Release Fogger against American Cockroaches, Body Lice, Bedbugs, and Yellow Jackets

A. American Cockroaches

(1) non-GLP

(2) **Methods:** Ten mixed-sex (5 adult male and 5 adult female) American roaches (*Periplaneta americana*) were placed in a plastic five-gallon arena. Eight (8) arenas were designated for fogger tests; four (4) arenas were designated as untreated controls. Treatment arenas were placed symmetrically around the test chamber measuring 8' x 15' (6000 ft^3). Product was discharged for 1 minute, 23 seconds during which it dispensed 76.82 grams of material. Insects were left in treatment chamber for a period of two hours, then transported to a separate untreated laboratory. All insects remained in their original containers throughout the study. Percent (%) KD was measured after 2 hours post treatment and percent (%) mortality was calculated at 24 hrs.

(3) **Results:** Treatment produced 100% knockdown of American roaches after 2 hrs and 97.5% mortality after 24 hrs.

(4) **Conclusions:** This study is **unacceptable** and does not support that the subject product kills American roaches. Although separate treatment arenas were called "replicates" by the laboratory personnel, there was only one treatment conducted in one chamber. As such, the experimental design only has one true replication. Also, none of the insects were removed from treatment arenas into clean arenas after the initial two-hr period. The level of exposure to the active ingredient over 24 hrs is not known because the amounts of any residual insecticide deposited into the arenas from the fog treatment is unknown. Therefore the mortality results may not be realistic.

B. Body Lice

(1) non-GLP

(2) **Methods:** Ten mixed-sex (5 adult male and 5 adult female) body lice (*Pediculus humanus humanus*) were placed in a 16 oz. glass arena. Eight (8) arenas were designated for fogger tests; four (4) arenas were designated as untreated controls. Treatment arenas were placed symmetrically around the test chamber measuring 8' x 15' (6000 ft^3). Product was discharged for 1 minute, 23 seconds during which it dispensed 76.82 grams of material. Insects were left in treatment chamber for a period of two hours, then transported to a separate untreated laboratory. All insects remained in their original containers throughout the study. Percent (%) KD was measured after 2 hours post treatment and percent (%) mortality was calculated at 24 hrs.

(3) **Results:** Treatment produced 100% knockdown of body lice after 2 hrs and 100% mortality after 24 hrs.

(4) **Conclusions:** This study is **unacceptable** and does not support that the subject product kills body lice. Although separate treatment arenas were called "replicates" by the laboratory personnel, there was only one treatment conducted in one chamber. As such, the experimental design only has one true replication. Also, none of the insects were removed from treatment arenas into clean arenas after the initial two-hr period. The level of exposure to the active ingredient over 24 hrs is not known because the amounts of any residual insecticide deposited into the arenas from the fog treatment is unknown. Therefore the mortality results may not be realistic.

C. Bed bugs

(1) non-GLP

(2) **Methods**: Ten mixed-sex (5 adult male and 5 adult female) bed bugs (*Cimex lectularius*) were placed in a 16 oz. glass arena. Eight (8) arenas were designated for fogger tests; four (4) arenas were designated as untreated controls. Treatment areans were placed symmetrically around the test chamber measuring 8' x 15' (6000 ft^3). Product was discharged for 1 minute, 23 seconds during which it dispensed 76.82 grams of material. Insects were left in treatment chamber for a period of two hours, then transported to a separate untreated laboratory. All insects remained in their original containers throughout the study. Percent (%) KD was measured after 2 hours post treatment and percent (%) mortality was calculated at 24 hrs.

(3) **Results**: Treatment produced 100% knockdown of bed bugs after 2 hrs and 100% mortality after 24 hrs.

(4) **Conclusion**: This study is **unacceptable** and does not support that the subject product kills bed bugs. Although separate treatment arenas were called "replicates" by the laboratory personnel, there was only one treatment conducted in one chamber. As such, the experimental design only has one true replication. Also, none of the insects were removed from treatment arenas into clean arenas after the initial two-hr period. The level of exposure to the active ingredient over 24 hrs is not known because the amounts of any residual insecticide deposited into the arenas from the fog treatment is unknown. Therefore the mortality results may not be realistic.

D. Yellow Jackets

(1) non-GLP

(2) Methods: Ten wild-caught adult yellow jackets were placed in a wire-screen cage. Eight (8) replicate cages were designated for fogger tests; four (4) cages were designated as untreated controls. Treatment arenas were placed symmetrically around the test chamber measuring 8' x 15' (6000 ft^3). Product was discharged for 1 minute, 23 seconds during which it dispensed 76.82 grams of material. Insects were left in treatment chamber for a period of two hours, then transported to a separate untreated laboratory. All insects remained in their original containers throughout the study. Percent (%) KD was measured after 2 hours post treatment and percent (%) mortality was calculated at 24 hrs.

(3) **Results**: Treatment produced 100% knockdown of yellow jackets after 2 hrs and 100% mortality after 24 hrs.

(4) **Conclusion**: This study is **unacceptable** and does not support that the subject product kills yellow jackets Although separate treatment arenas were called "replicates" by the laboratory personnel, there was only one treatment conducted in one chamber. As such, the experimental design only has one true replication. Also, none of the insects were removed from treatment arenas into clean arenas after the initial two-hr period. The level of exposure to the active ingredient over 24 hrs is not known because the amounts of any residual insecticide deposited into the arenas from the fog treatment is unknown. Therefore the mortality results may not be realistic.

MRID 47385001 Classification: Unacceptable. Although the study design was logical, there are insufficient replications to support efficacy claims, therefore this study must be removed from the data matrix. Although insects were removed from the treatment chamber after 2 hrs, they remained in their original treatment arenas for the entire 24 hrs. As a result, the true extent of exposure cannot be characterized.

44145101. Multicide® Intermediate 2471 EPA File Symbol 1021-1557 Product Performance / Efficacy Reports

(1) Non-GLP

(2) **Methods**: Direct spray applications of formulations F-2471 (2% phenothrin) and TOAPS (0.2% phenothrin; 1.6% piperonyl butoxide) were conducted against German cockroaches *Blatella germanica*, and harvester ants (no species specified). Details regarding the methodology were not disclosed in MRID. An external document was cited as source for methods. In separate tests, formulations F-2471 and OAT-II were tested against cat fleas *Ctenocephalides felis* and brown dog ticks *Rhipicephalus sanguineus*. Active ingredient(s) of the formulation OAT-II were not disclosed.

(3) **Results:** Efficacy results from MRID 41445101 were not assessed by the reviewer for the following reasons: 1) Active ingredients within test products respectively TOAPS and OAT-II contained synergists and were unknown. 2) Efficacy of F-2471 was based upon direct-spray applications. In contrast, the defined use-pattern for 68543-35 is a spatial fogger. Because the use patterns of the tested formulation and product 68543-35 are different, study data may not be bridged to support label claims for 68543-35.

(4) **Conclusion**: Study was not reviewed. Results are not applicable.

MRID 41445101 is classified as **unacceptable** and does not support efficacy claims against German cockroaches, harvester ants, fleas, and brown dog ticks. Therefore, MRID 41445101 should be removed from the data matrix. The active ingredients of the test formulations did not match the product and the use pattern for all test formulations was different from the use pattern for 68543-35.

45407804. Multicide® Lice and Dust Mite Spray 27911 EPA Reg No. 1021- Product Performance / Efficacy Reports.

(1) Non-GLP

(2) **Methods**: Direct spray applications of formulations F-21281 (0.4% phenothrin) and X-54241 (0.4% phenothrin; 1.6% MGK 264) were conducted against the human body louse *Pediculus humanus humanus*. Fabric surfaces were directly sprayed with test formulations, then mortality was counted over a period of 24 hours.

(3) **Results**: Efficacy results from MRID 45407804 were not assessed by the reviewer for the following reasons: 1) Active ingredients within test formulation X-54241 contained a synergist which is not present in product 68543-35; 2) Efficacy of formulations F-21281 and X-54241 was based upon direct-spray applications to fabric. In contrast, the defined use-pattern for 68543-35 is a spatial fogger. Because the use patterns of the tested formulations and product 68543-35 are different, study data may not be bridged to support label claims for 68543-35.

(4) **Conclusion**: Study was not reviewed. Results are not applicable.

MRID 45407804 is classified as **unacceptable** and does not support efficacy claims against human body lice. Therefore, MRID 45407804 should be removed from the data matrix. The active ingredients of the test formulations contained a synergist and the use patterns for the test formulations were not consistent with the use pattern for 68543-35.

IV. EXECUTIVE SUMMARY

MRID 45590804: This study is **unacceptable** and should be removed from the data matrix for 68543-35. Test formulations contained different active ingredients, multiple active ingredients, and/or synergists. Therefore efficacy data could not be bridged to support claims on subject product 68543-35. Use patterns of test formulations were designed for direct-spray applications. In contrast, the use pattern of 68345-35 is a spatial fogger. This inconsistency further prohibits the bridging of data from MRID 45590804 to support the subject product 68543-35.

MRID 47697301: This study is **acceptable** and should remain on the data matrix for product 68543-35. Claims must not exceed a volume of 3000 ft^3 which corresponds to the space in which treatments were conducted. Reviewer notes that in previous studies, failure to remove insects from the treatment arena would invalidate the study because continued exposure would not represent a realistic scenario. However, in this case, retaining fleas inside carpeted areas represents a real-world scenario for residential dispersal of a fogger.

MRID 47385001 Although the study design was logical, this study is classified as **unacceptable** because there are insufficient replications to support efficacy claims. As a result, this study must be removed from the data matrix. Test arenas were removed from the treatment chamber after 2 hrs, but the insects remained within their original treatment arenas for the entire 24 hrs. As a result, the true extent of exposure cannot be characterized.

MRID 41445101 is classified as **unacceptable** and does not support efficacy claims against German cockroaches, harvester ants, fleas, and brown dog ticks. Therefore, MRID 41445101 should be removed from the data matrix. The active ingredients of the test formulations did not match the product and the use pattern for all test formulations was different from the use pattern for 68543-35.

MRID 45407804 is classified as **unacceptable** and does not support efficacy claims against human body lice. Therefore, MRID 45407804 should be removed from the data matrix. The active ingredients of the test formulations contained a synergist and the use patterns for the test formulations were not consistent with the use pattern for 68543-35.

V. LABEL RECOMMENDATIONS

(1) Make the following changes to the Directions for Use:

- Delete directions for use against ticks, ants, lice, mosquitoes, flies, gnats, hornets, wasps, bees, and yellow jackets within treatment areas up to a maximum volume of 6000 ft^3.
- Add "listed" to describe "bugs" in claim: "Kills bugs after you leave (the) (room) (house) (area)"

(2) The following marketing claims are acceptable:

- Kills claims against fleas are supported within treatment areas up to a maximum volume of 3000ft^3.

(3) The following marketing claims are unacceptable: All marketing claims against ticks, ants, lice, mosquitoes, flies, gnats, hornets, wasps, bees, and yellow jackets are unacceptable.

- "Reduces heavy (insect) infestations"
- "(Formulated) (for use against) (to control) heavy (flea) (infestations) (populations)"

- Kills 16+ types of listed insects

(4) The following MRIDs should be removed from the data matrix, as they are classified as "**unacceptable**" to support the product: 45590804; 47385001; 41445101, and 45407804.

(5) Make other comments/recommendations as appropriate: MRID 47697301 presented a logical study that was properly replicated and represented a realistic scenario for application of fogging devices and products. In contrast, the rest of the MRIDs were not assessed by the reviewer because the use patterns or active ingredients did not match those on the label.